

Remarks

Upon entry of the foregoing amendment, claims 1-11 pending in the application, with claims 1 and 8 being the independent claims. The claims have been amended to correct grammatical errors, and claim 8 has been amended to clarify that the amounts and weight ratio of glimepiride and metformin provide synergistic control of blood glucose levels. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Applicant respectfully asserts that this Restriction Requirement based on lack of unity of invention is unfounded. U.S. Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention, 37 C.F.R. § 1.475(b)(2):

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .

(2) A product and process of use of said product; . . .

Furthermore, the Administrative Instructions Under the PCT provide:

(c)(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination. (see Administrative Instructions Under the PCT, Annex B.)

The international Search and Preliminary Examination Guidelines (www.wipo.int/pct/en/texts/gdlines.htm) provide the following examples:

Example 1

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Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

Example 15

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

Here, Groups I and II possess unity of invention because all of their respective claims contain reference to the special technical feature, i.e., a synergistic combination of metformin and glimepiride, a required limitation.

The Examiner asserts that there is lack of unity between the product, the composition of metformin and glimepiride, and the method of using the product because the product was known in the art. Specifically, the Examiner asserts that "a composition of glimepiride and metformin is known in the art" (Office Action at page 2) citing Whitcomb (U.S. Pat. No. 6,011,049, hereinafter '049). Applicants' respectfully traverse the examiners assertion that the inventions of Group I and Group II do not relate to a single general inventive concept.

Applicant's claims are directed to a composition comprising a combination of metformin and glimepiride in amounts and weight ratio sufficient to provide synergistic control of blood glucose. Although the general use of sulfonylureas and biguanides in combination are known in the art, the art does not teach a combination of metformin and glimepiride in synergistic amounts and weight ratios as recited in Applicant's claims.

The '049 reference does not describe a combination of metformin and glimepiride in amounts and weight ratio that result a synergistic effect. Because the prior art does not teach a composition comprising a synergistic combination of metformin and glimepiride restriction between Group I and Group II is not proper.

Applicants assert that the Restriction Requirement is improper because unity of invention exists amongst the claims. Reconsideration and withdrawal of the Restriction Requirement, and immediate examination of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Conclusion

Prompt and favorable consideration of this Preliminary Amendment and reconsideration and withdrawal of the Restriction Requirement is respectfully requested. Applicant believes the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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